NDA 19-810/S-057

Astra Pharmaceuticals, L.P.
Attention: Gary P. Horowitz, Ph.D.
725 Chesterbrook Blvd.
Wayne, PA 19087-5677

FEB - 3 1999

Dear Dr. Horowitz:

Please refer to your supplemental new drug application dated July 31, 1998, received August 3,1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prilosec (omeprazole) Delayed-Release Capsules.

We acknowledge receipt of your submission dated October 19,1998 containing revised final printed labeling (no. 7910930) which corrects errors discovered in the final printed labeling (no. 7901928) submitted in this supplement on July 3 1,1998.

We note that this supplement was submitted as a 'Special Supplement - Changes Being Effected under 21 CFR 3 14.70(c).

This supplemental new drug application provides for revision of the ADVERSE REACTIONS section of the package insert to add the phrases "allergic reactions, including, rarely, anaphylaxis (see also *skin* below)" and "purpura and/or petechiae (some with rechallenge)." Your submission stated November 1,1998 as the implementation date for the changes.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted October 19,1998, no. 7910930). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.